

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SIGMA-TAU PHARMACEUTICALS,
INC.

Plaintiff,

v.

BERNARD A. SCHWETZ, D.V.M.,
Ph.D.,
Acting Principal Deputy Commissioner
of Food and Drugs, et al.

Defendants.

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Civil Action No. CCB-01-CV-1377
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DISTRICT OF MARYLAND
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**STIPULATION AND ORDER REGARDING
TREATMENT OF PREVIOUSLY FILED MOTIONS
AS MOTIONS FOR SUMMARY JUDGMENT**

In accordance with discussions had at a conference with the Court on July 13, 2001, subsequent to the hearing and decision on Plaintiff's Motion for Preliminary Injunction, the parties have decided to stipulate and agree that motions and supporting memoranda previously filed with the Court be construed and considered by the Court as cross-motions for summary judgment and briefs in support of such motions. This will allow the Court to issue a final judgment in this matter without the need for additional submissions by the parties on issues that all parties and the Court agree have been fully and thoroughly briefed and argued to the Court. Accordingly, the parties stipulate and agree as follows:

1. The motion of Plaintiff, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") for preliminary injunction, filed with this Court on or about June 11, 2001, shall, in addition to being considered as a Motion for Preliminary Injunction,

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also be treated as a Motion for Summary Judgment by which Sigma-Tau requests that the Court enter judgment in its favor declaring the Food and Drug Administration's ("FDA") approval on March 29, 2001 of the abbreviated new drug applications ("ANDAs") of Gensia Sicor Pharmaceuticals, Inc. ("GS") and Bedford Laboratories ("Bedford") to be invalid as arbitrary and capricious, an abuse of FDA's discretion, or otherwise not in accordance with the Federal Food, Drug and Cosmetic Act (including sections 505(j) and 527(a) of that Act), or the Administrative Procedure Act (including section 706 of that Act). Additionally, this Motion for Summary Judgment shall be construed as requesting a permanent injunction against approval of the GS and Bedford ANDAs until December 2006, that being the expiration of the period of exclusivity accorded Sigma-Tau under the Orphan Drug Act for use of its levocarnitine injection drug product known as Carnitor® for the treatment of End Stage Renal Disease ("ESRD") patients. Finally, the Motion for Summary Judgment shall be construed as requesting such other and further relief as the Court may deem appropriate.

2. In support of its Motion for Summary Judgment, and in opposition to Defendants' Cross-Motion for Summary Judgment, Sigma-Tau relies upon and incorporates the memoranda and supporting materials previously submitted to the Court in support of its Motion for Preliminary Injunction and Motion for Temporary Restraining Order, the oral arguments before the Court on those motions, and the Administrative Record for the approval of the GS and Bedford ANDAs.

3. The motion of GS to dismiss filed with this Court on or about August 9, 2001 shall be converted into and treated as a Cross-Motion for Summary Judgment on behalf of GS. Further, Defendants Bernard A. Schwetz, D.V.M., Ph.D. and Tommy G. Thompson (the "Federal Defendants") join in and adopt this Cross-Motion for Summary Judgment.

4. By their Cross-Motion for Summary Judgment, GS and the Federal Defendants ask that this Court enter a final judgment in their favor and find that the approvals of the GS and Bedford ANDAs on or about March 29, 2001 were valid and were not arbitrary and capricious, an abuse of discretion, or otherwise a violation of law and that such approvals were appropriate and permissible under the Federal Food, Drug and Cosmetic Act (including sections 505(j) and 527(a) of that Act), and the Administrative Procedure Act (including section 706 of that Act). Further, GS and the Federal Defendants, by their Cross-Motion for Summary Judgment, ask that this Court deny Sigma-Tau's request for a permanent injunction. Finally, GS and the Federal Defendants, by their Cross-Motion for Summary Judgment, ask this Court for such other and further relief as the Court may deem appropriate.

5. In support of their Cross-Motion for Summary Judgment, and in opposition to Sigma-Tau's Motion for Summary Judgment, GS and the Federal Defendants rely upon and incorporate their memoranda and supporting papers filed with this Court in opposition to Sigma-Tau's Motion for Preliminary Injunction and those filed in opposition to Sigma-Tau's Motion for Temporary Restraining Order,

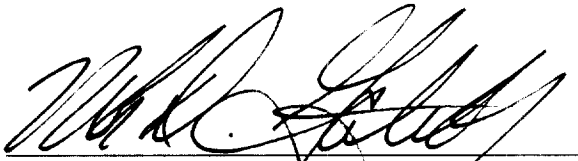
the oral arguments before the Court on those motions, and the Administrative Record for the approval of the GS and Bedford ANDAs.

6. All parties agree that Sigma-Tau's Motion Summary Judgment and GS's and the Federal Defendants' Cross-Motion for Summary Judgment have been fully briefed and are ripe for decision by this Court.

It is SO ORDERED this 3rd day of August, 2001



Judge Catherine C. Blake

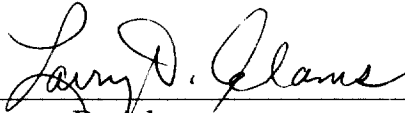


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